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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,920	02/01/2000	ARNE EEK	1103326-0603	6956

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,920	EEK ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-32 and 35-40* is/are pending in the application.

4a) Of the above claim(s) *28-30,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-27,31,32,35 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 06/17/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. US 6,365,184, in view of Woolfe et al. US 6,387,410.

Depui teaches an oral composition comprising combination of NSAID and proton pump inhibitor, such as omeprazole, lansoprazole, pantoprazole, or salts thereof; carriers; and excipients (columns 5-8). The composition is useful for the treatment of gastrointestinal disorders (column 1, lines 10-18). The composition can be in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Depui does not teach combination of proton pump inhibitor and gastric antisecretory prostaglandin.

Woolfe teaches composition comprising combination of NSAID and prostaglandin, such as misoprostol (columns 1-3). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Depui's composition with the use of prostaglandin in view of the teachings of Woolfe, because Woolfe teaches the advantageous result in the use of misoprostol for the treatment of gastrointestinal side-

effects associated with NSAID. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, and prostaglandin for the treatment of gastrointestinal disorders.

Claims 1-4, 11-27, 35, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akira Tari et al. (Digestive Diseases and Sciences, Vol. 42), and Depui et al.

Tari teaches omeprazole-enprostil combination useful for the treatment of peptic ulcer (pages 1742-1744). Tari is silent as to the specific oral dosage form.

Depui teaches oral dosage form comprising omeprazole and NSAID in the form of pellet, granules, coated pellet, compressed tablet, or capsule (columns 9-14). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify the composition of Tari as an oral dosage form in view of the teachings of Depui, because controlled/sustained release oral dosage is useful for the treatment of gastrointestinal disorders.

Claims 1-4, 6-27, 31, 32, 35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. in view of Woolfe et al., and Shell US 5,582,837.

Depui and Woolfe are relied upon for the reasons stated above. The references are silent as to the teachings of the use of calcium channel blocker.

Shell teaches sustained release dosage form containing calcium channel blockers useful for the treatment of gastric diseases (columns 3-4). Hence, it would have been prima facie obvious for one of ordinary skill in the art to prepare composition

of Depui and Woolfe with calcium channel blocker in view of the teaching of Shell, because the references teaches the advantageous result of oral formulation useful for treating gastrointestinal disorders. The expected result would be a single dosage form comprising combination of proton pump inhibitor, NSAID, calcium channel blocker, and prostaglandin for the treatment of gastrointestinal disorders.

Response to Arguments

Applicant's arguments filed 06/17/04 has been fully considered but they are not persuasive.

Applicant argues that claims 1 and 40 have been amended to recite the closed-ended "consisting of" only to the combination of active agent, to exclude additional unspecified ingredients, which would affect the basic and novel characteristics of the invention defined in the balance of the claim. Thus, the patentable feature of claims 1 and 40 is the combination of an ATP-ase inhibitor and prostaglandin in a single dosage form, and therefore, the combination of Depui and Woolfe; or the combination of Akira Tari and Depui et al., does not suggest the claimed invention since the references disclosed the use of NSAIDs. However, it is noted that the compositions of claims 1 and 40 use the transitional phrase "comprising of", which is an open-ended that allows other ingredient, including active ingredients, such as NSAID. From a reading of applicant's original specification, it is clear that 1) applicant did not intend to exclude NSAIDs of the prior art, and 2) that the prior art NSAIDs are clearly not detrimental. Applicant argues that the specification does not disclose or suggest the claimed dosage

form to include an NSAID, rather, it suggests "co-administration" of the claimed dosage form and NSAID dosage form. Accordingly, what is the detrimental effect in the present/absent of NSAID? The examiner is unable to determine the unexpected result of the claimed invention over the cited prior arts. Again, applicant's attention is called to the "comprising of" transitional language recites in the rejected claims. "Comprising" is a term of art used in claim language which means that the named elements are essential, but *other elements may be added and still formed a construct within the scope of the claim.* Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ448, 450 (Bd. App. 1948). "Comprising" leaves the claim open for the inclusion of *unspecified ingredients even in major amounts.*

Applicant argues that Tari does not disclose an oral dosage form of the combination of omeprazole-enprostil. Contrary to the applicant's argument, Tari does disclose combination of omeprazole-enprostil for oral administration (seepages 1742-1744). Tari is only deficient in the sense that Tari does not explicitly teach the dosage form. However, it would have been obvious for one of ordinary skill in the art to formulation the combination of omeprazole-enprostil into a dosage form at least suitable for oral administration. Furthermore, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the combination of Depui, Woolfe and Shell does not suggest the claimed invention because the amended claim excludes an NSAID. For the above disclosed reasons regarding to the transitional phrase "consisting essentially of", it is the examiner's position that the combination of Depui and Woolfe, and Shell does suggest the claimed invention. In response to applicant's argument regarding the examiner's conclusion of obviousness, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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